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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445,297 12/02/99 VANDECRUYS

R JAB-1282

EXAMINER

HM12/0709

AUDLEY A CIAMPORCERO  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK NJ 08933-7003

KULKOSKY, P

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

00/445207

Applicant(s)

Roger Petrus G. vanderkruijs

Examiner

P. Kulkesky

Group Art Unit

1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on April 09, 2001.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1,2,4-15,20 is/are pending in the application.
- Of the above claim(s) 21 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1,2,4-15,20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1615

Claims 1, 2, 4-15, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Putteman et al 5,814,330 or EPA 0,689,844 or WO 94/12217.

The term "is a glass thermoplastic phase" is not limited to products disclosed in the specification which are of a certain solid solution physical condition.

Thus, those skilled in the art are enabled to prepare compositions so vaguely defined as "in a glass thermoplastic phase" by following the preparative methods of the cited Prior Art and then evaporating and/or heating the cyclodextrin drug complexes.

The Figures and specification Tables represent compositions <sup>having</sup> of properties to which the claims are not limited. Therefore, it is necessary to limit the composition of the claims in such a way as to exclude solvent - containing cyclo - dextrin complex products of the cited Prior Art and list each ingredient by a Markush group of same and in effective amounts. A dissolution rate limitation would further distinguish the composition of the instant claims. Solvents are not excluded simply by use of the term "glass transition thermoplastic". A solid solution whose physical characteristics are clear and may be measured as being in certain ranges is necessary to be designated to overcome the rejection on the basis of being unobvious from compositions of the cited Prior Art whose form may be "thermoplastic".

Claims 1, 2, 4-15, 20 are rejected under 35 U.S.C. 112, paragraph 2.

The improved result working property of dissolution time range is not claimed. This property is considered to be critical to defining the composition as being unobvious in comparison to Prior Art Cyclodextrin complexes.

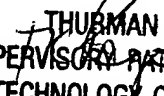
Art Unit: 1615

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Kulkosky/LR

June 21, 2001

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600